

**REMARKS**

Claims 1-2, 4, and 6-11 are pending in the application.

The Applicants appreciate the Examiner's indication that claim 4 contains allowable subject matter. By way of this amendment, new dependent claims 8-10 have been added that depend on claim 4.

The remaining claims stand rejected over various references.

By way of this amendment, the claims have been amended to further define the invention. It is respectfully submitted that the amended claims are clearly patentable for at least the following reasons.

Claim 1 has been amended to recite subject matter similar to that previously recited in claim 3, plus additional subject matter. That is, claim 1 has been amended to recite that the system comprises a core pin with a channel at least partially forming a blood path and a side hole in fluid communication with the proximal end of the introducer assembly via the channel.

Claims 1, 2, and 7 stand rejected under section 102 as being anticipated by Moriuchi. This rejection has been clearly overcome because Moriuchi does not disclose, for example, a core pin.

Claims 1-3 and 5-7 stand rejected under section 103 as being obvious over Van Tassel in view of Hammerslag and Moriuchi.

In the invention of claim 1, a pressure sensor is in fluid communication with and coupled to a proximal end of the introducer assembly to measure blood pressure and output a waveform indicative of blood pressure at a distal end of the introducer assembly. Van Tassel does not have these features. As discussed at the bottom of column 5 of Van Tassel, Van Tassel discusses watching the rise of blood in a transparent body. This technique thus does not use a pressure sensor, as claimed. In the bottom of column 5, Van Tassel does describe alternative ways of determining pressure. However, these ways (using radially spaced

electrodes or a miniaturized pressure sensor) involve measuring pressure at the distal end not from the proximal end of the assembly. It appears that blood does not reach the proximal portion of Van Tassel because lumen 72 (which contains blood) would be vented by port 94 and thus blood would not reach the proximal end of the assembly. Please see the second and third full paragraphs of column 6.

Hammerslag and Moriuchi are completely different types of devices compared with Van Tassel, and one of ordinary skill in the art would not have combined Van Tassel with Hammerslag and/or Moriuchi. More specifically, Van Tassel relates to a type of device which has an introducer sheath 12 and a relatively large diameter injection device 14. (Thus, Van Tassel is somewhat similar to the device shown in Figure 8 of the present application in that Van Tassel and the present invention (of claim 1) have a large inside diameter member 12/10 and inserted therein another large diameter, relatively rigid, member 14/27.)

Figure 8 of Hammerslag (showing an introducer sheath 250, a guidewire 252, and pressure sensor display 268) and associated text provide no guidance or teaching as to how to use/modify a core pin to measure pressure in the manner claimed in amended claim 1. In addition, the Applicants understand the discussion in the third full paragraph of column 18 of Hammerslag, to refer to monitoring blood pressure to monitor the patient's condition, and thus the equipment in Figure 8 is not available for other purposes. Also, Hammerslag contains no teaching directed to detecting the position of a distal end of an introducer via measurement of blood pressure. Column 10, third full paragraph, contains no reference to detecting the position of a distal end of an introducer via measurement of blood pressure.

Furthermore, none of these three documents contains disclosure similar to that set forth in paragraph 0027 of the present as filed application. In other words, none of the prior art teaches the arrangement described in the present application wherein different waveforms are displayed on a display such that a determination can be made as to whether the seal is working properly from such waveforms. The display of a waveform is an important aspect of the invention because the waveform provides the best indication of the position of the introducer assembly, in contrast to for example a numerical indication.

Claims 1-3, 5, and 7 stand rejected under section 103 as obvious over Miyata in view of Moriuchi. This rejection is respectfully traversed with respect to the amended claims because neither of these references discloses the claimed core pin, or similar structure.

Claims 1-3 and 5-7 stand rejected under section 103 over Hammerslag and Moriuchi. This rejection is respectfully traversed for at least the reason that neither of these references discloses at least the claimed core pin.

Claims 1 and 2 stand rejected under section 103 based on Scribner in view of Moriuchi. This rejection is respectfully traversed for at least the reason that neither of these references discloses or suggests at least the claimed core pin.

Claims 1-3, 5, and 6 stand rejected under section 103 based on Li. This rejection is respectfully traversed because the Li device does not disclose or suggest at least a core pin with a channel at least partially forming a blood path. In Li, the blood flow path is provided in a narrow tube 15 which is part of a cannula 11 (which is analogous to the claimed introducer), not in a structure which goes inside cannula 11.

Claims 1-3, 5, and 7 stand rejected under section 103 as being unpatentable over Edwards in view of Hammerslag and Moriuchi. This rejection is respectfully traversed. In Edwards, pressure sensors are provided at the distal end of the assembly, such as pressure sensor 38 shown in Figure 1A (or pressure is sensed via a bloodspurt, as discussed at the top of column 13). Figure 8 of Hammerslag (showing an introducer sheath 250, a guidewire 252, and pressure sensor display 268) and associated text provide no guidance or teaching as to how to use/modify a core pin to measure pressure in the manner claimed in amended claim 1. In addition, the Applicants understand the discussion in the third full paragraph of column 18 of Hammerslag, to refer to monitoring blood pressure to monitor the patient's condition. Hammerslag contains no teaching directed to detecting the position of a distal end of an introducer via measurement of blood pressure. Column 10, third full paragraph, contains no reference to detecting the position of a distal end of an introducer via measurement of blood pressure.

A terminal disclaimer is submitted herewith to render the double patenting rejections moot.

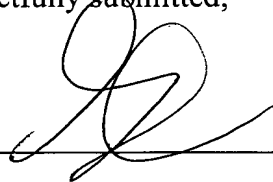
Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

By



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